Testimony of Dr. David Friedman

Subcommittee on Oversight and Investigations
Committee on Energy & Commerce
U.S. House of Representatives

"Human Tissue Samples: NIH Research Policies and Practices"

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Mr. Chairman and Members of the Subcommittee, thank you for the opportunity to come before you today to discuss the facts relating to the use of cerebrospinal fluid (CSF) and plasma samples in a collaboration between Dr. Sunderland, at the NIMH, and Pfizer Inc. I have great respect for the work of this Subcommittee and the process of scrutiny underlying this hearing, as I believe that it will serve to clarify issues and resolve questions about the process and intent of these key studies.

I am appearing before you for several reasons. First, I have first-hand information regarding some scientific issues relating to the interaction between Pfizer and Dr. Sunderland. As an employee of Pfizer, from 1995 to 2001, I initiated discussions between Dr. Sunderland and Pfizer regarding a possible scientific collaboration to search for and evaluate possible biomarkers of Alzheimer's disease.

Second, I have great respect for Dr. Sunderland as a scientist and clinician and for his contributions to this important basic research. I also have great respect for each of the key contributors to this experiment, including my former Pfizer colleagues, and the NIMH staff and associates of Dr. Sunderland who participated in this effort. I also recognize and respect the important contribution of the individual Alzheimer's patients and their respective families who contributed important CSF and plasma samples and underwent extensive testing over the past few decades, resulting in data and samples that are the subject of the discussion today.

Finally, I appear here today in part because not doing so might be misinterpreted as not supporting the nature, process, and intent of this research effort.

I would like to make a few brief comments on the intent of the study as it relates to the issue of biomarkers. The information we sought in this experiment was essential to enable several medically important aspects of treatment of Alzheimer's disease, a goal with enormous significance to patients, their families and to society as a whole. Specifically:

- We sought to uncover new tools to enable the diagnosis and early detection of Alzheimer's disease. These tools are viewed as essential in the development of new therapeutics due to the current limitations in the unequivocal diagnosis of Alzheimer's disease.

- We also sought to identify biomarkers for disease progression rate, essential to conduct cost-effective and efficient clinical drug trials given the heterogeneity of progression rates within this patient population.

- We also sought biomarkers to stratify patients by specific disease stages, knowing that various disease stages were likely to manifest differing components of the disease process and thus the potential to respond to different classes of therapeutics.

- Last, we sought to identify markers of apparently normal individuals, exhibiting no measurable cognitive defect, who were at risk of developing Alzheimer's disease as a result of family history and/or genetic predisposition to the disease. This in turn might enable the treatment of cognitively normal yet affected individuals prior to their slow, progressive, and debilitating decline.

It is important to recognize that these classes of markers serve ***several*** important roles.

- First, they may facilitate and enable the proper clinical testing of potential Alzheimer's therapeutics under currently approved FDA guidelines.

- Second, they may enable and inform regarding the proper clinical diagnosis of patients by the general medical community, and may facilitate the appropriate determination of medication for an individual's specific stage of the disease.

- Finally, when these medications become available, these markers can also serve to enable physicians to individually monitor the response of their patients to insure optimal and cost-effective treatment.

Given the magnitude of the societal burden of Alzheimer's disease now and in the near future, these are important tools to be uncovered and developed. Dr. Sunderland recognized the significance of biomarkers and actively sought to identify biochemical markers as well as other types of markers in order to treat patients more effectively, consistent with his role as an academic clinician at the NIMH. This was clearly obvious from his academic publications, which in turn was the vehicle through which I, as a Pfizer employee, initially contacted him regarding an effort to uncover these important tools to assist in the diagnosis and treatment of Alzheimer's patients.

Thank you for the opportunity to testify today. I would be happy to answer any questions you may have regarding this matter.